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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,526	02/26/2004	C. Allen Chang	3102/2020	6448

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/787,526

Applicant(s)

CHANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,7-9,11,12 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9 and 11 is/are rejected.
- 7) ☒ Claim(s) 1, 3, 4, 7-9, 11, 12, and 15-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/17/06 wherein claims 1, 4, 9, and 12 are amended and claims 2, 5, 6, 10, 13, 14, and 21-46 are canceled.

**Note:** Claims 1, 3, 4, 7-9, 11, 12, and 15-20 are pending.

## APPLICANT'S INVENTION

2. Independent claim 1 is directed to an excipient having the formula  $X_m[X'(L')]_n$ . Independent claim 9 is directed to a composition comprising a metal ion, M, complexed to an organic ligand, L and a complex salt excipient having the formula  $X_m[X'(L')]_n$ .

## RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

3. The Applicant's arguments and/or amendment filed 8/17/06 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered the rejections WITHDRAWN for the reasons set forth below.

### **112 Rejections**

The 112, second paragraph, rejection is MOOT in view of the new grounds of rejection below.

**Note:** The rejection below will hopefully clarify that the claims are vague and indefinite because the formula of the excipient does not involve the variable L which Applicant is attempting to incorporate into defining the excipient.

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**103 Rejection**

The 103(a) rejection is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

**NEW GROUNDS OF REJECTIONS**

**112 Written Description Rejection**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, and 8 disclose that 'L' is an organic ligand which may be L or another organic ligand which as a greater affinity for M than for calcium or zinc'.

However, the excipient formula appearing in independent claim 1,  $X_m[X'(L')]_n$  does not involve the variable L. Thus, based on the description set forth in the instant application, the variable L has not been described in such a way as to reasonably convey the metes and bounds of the claims and the limitations that Applicant is placing on the excipient based on the variable L which is absent in the excipient formula.

**112 Rejections**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3, 4, 7-9, and 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 7, and 8: The claims as written are ambiguous because independent claim 1 is directed to an excipient having the formula  $X_m[X'(L')]_n$ . However, in defining the variables of the excipient formula, Applicant has included the variable L which is not included in the excipient formula. Instead, Applicant is attempting to further define the variable L' of the excipient by defining another structure M(L) which is not a portion of the excipient formula. Applicant is respectfully requested to delete the references to the variable L which do not appear in the excipient formula because it makes the claims confusing.

Claims 3 and 11: The claims are ambiguous because it is unclear what polyaminopolycarboxylic carboxylic acid derivatives Applicant is referring to which are compatible with the instant invention.

Claim 9, line 3: Did Applicant intend to insert 'and' after the phrase 'organic ligand, L'?

Claims 1, 3, 8, 9, and 11: The claims as written are ambiguous because of the phrase 'L' is an organic ligand which may be L or another organic ligand which has a greater affinity for M than for calcium or zinc". In particular, the phrase is ambiguous

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because it is unclear which organic ligands Applicant is referring to that are compatible with the instant invention (see independent claims 1 and 9). In addition (see independent claim 1, for example), since it is the excipient that is being claimed and the formula of the excipient does not include the variable M, it is unclear what metals Applicant is referring to and why Applicant is referring to the variables L and M which are not involved in the formula of the excipient,  $X_m[X'(L')]_n$ .

### CLAIM OBJECTIONS

8. Claims 12 and 15-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

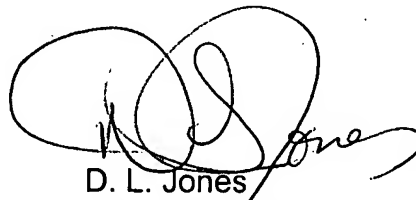
### COMMENTS/NOTES

9. It should be noted that no prior art has been cited against the instant invention. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious an excipient or composition having the limitations as set forth in independent claims 1 and 9.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'D. L. Jones', is written over the printed name and title.

D. L. Jones  
Primary Examiner  
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October 30, 2006